



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,268	02/16/2001	Jonathan W. Jarvik	2087-010262	5282

7590 01/15/2004

Barbara E. Johnson
WEBB ZIESENHEIM LOGSDON ORKIN & HANSON, P.C.
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818

EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/788,268

Applicant(s)

JARVIK, JONATHAN W.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 13-73, 76, 77 and 80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 74, 75, 78 and 79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-80 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION
RESTRICTION/ELECTION

Applicant's election with traverse of Group I (Specie A: mass), (claims 1-12, 74, 75, 78, and 79) in the Paper filed 10/14/03 is acknowledged. The traversal is on the ground(s) that Groups I and II are classified in the same Class/Subclass and have the same genetic information in common. This is not found persuasive because the basis for the restriction is distinctness of subject matter. Divergent and distinct subject matter that is separately published and searched is frequently found within the same Class/Subclass. Thus, the argument regarding the same classification of Groups I and II is moot due to not being directed to the distinctness of subject matter basis for this restriction requirement. The second traversal argument is directed to Groups I and II having the same genetic information in common. In response, this argument also is not directed to the basis for the restriction requirement between Groups I and II as set forth in the previous office action, mailed 9/9/03, and thus moot. The different modes of operation, functions, or effects were summarized in said previous office action. For example, instant claim 1 in Group I is clearly directed to sequence determination in the first and seventh lines thereof whereas, in contrast, claim 15 in Group II is directed to genetic analysis to determine coding capacity. It is noted that claims 76 and 77 depend from claim 15 and inadvertently were previously cited in Group I. Applicant, however, has apparently recognized this error and excluded claims 76 and 77 from the set of elected claims. Applicant also, however, did not exclude claims 13 and 14 from the elected set of claims. It is noted that claims 13 and 14 are directed to non-elected

species of physical property determination within Group I and are therefore non-elected due to the Specie A election.

The requirement is still deemed proper and is therefore made FINAL.

VAGUENESS AND INDEFINITENESS

Claims 1-12, 74, 75, 78, and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 1, the method is directed to the determination of the sequence of a polynucleotide. Consideration of the actual claim steps reveals a lack of reference to a "polynucleotide" per se. It is noted that part "a" cites a "nucleic acid fragment" as well as a "known reference sequence", both of which may be a polynucleotide, but are not clearly described as the polynucleotide cited in said line 1. Part "c" of claim 1 determines a sequence of said fragment but there is no connection stated regarding whether said fragment is the polynucleotide of line 1 of claim 1 or only a fragment thereof from which some type of unstated inferred sequence of the polynucleotide is produced. Alternatively, the "reference sequence" of part "a" of claim 1 may be meant as the polynucleotide of line 1 of claim 1. This, however, is confusing because said part "a" recites this sequence as a "known" reference sequence. What determination is meant for a sequence which is already "known". Thus, the preamble of claim 1 seems to be different in metes and bounds from the actual recited claim steps. It is unclear which part of claim 1 controls its metes and bounds and therefore supports this rejection. This unclarity is also in claims which depend directly or indirectly from claim 1

Art Unit: 1631

and are also rejected therefore hereinafter. Clarification via clearer claim wording is requested.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7, and 9-12 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by either of Little et al. (P/N 6,207,370) or Garvin (P/N 6,329,180).

In the title and abstract of Little et al. the invention therein is described as being directed to detection and identification of mutations in a genetic region. Thus, the mutation detection is therein directed to detection of nucleic acid sequence compared to a known sequence which has been mutated as required in instant claim 1, part a. Mass spectrometric determination of polypeptides is compared to the expected mass of known identity which is the same subject matter area as instantly claimed. In column 5, lines 9-23, the expression of a nucleic acid fragment being an RNA molecule is disclosed as required in instant claim 1, part b., and instant claim 7. The translation product polypeptide is analyzed via mass detection in mass spectrometry as disclosed in column 5, lines 35-61. The encoded sequence is then utilized to compare to a known nucleic acid sequence for mutation detection in column 5, line 62, through column 6,

Art Unit: 1631

line 16, as also required in part c of instant claim 1 as well as claim 2. Thus, instant claims 1, 2, 7, 11, and 12 are thereby anticipated.

Similarly, Garvin utilizes mass spectrometry detection of nucleic acid sequences for mutation detection via polypeptide fragment mass determination as summarized in the abstract. The expression of polypeptide(s) with mass spectrometry mass determination and nucleic acid reference comparison for mutation detection is further detailed in the reference in column 5, line 10, through column 7, line 59, thus also anticipating instant claims 1, 2, 11, and 12. cDNA preparation as the nucleic acid fragment is disclosed in Garvin in column 4, lines 52-67, as also required in instant claim 4. In either reference polypeptides are expressed thus requiring the nucleic acid fragment to comprise an exon as in instant claim 3. Purification of the analyzed peptide as in instant claims 9 and 10 is disclosed in Garvin in column 5, lines 34 et seq.

INFORMALITIES

The disclosure is objected to because of the following informalities:

Claim 1 contains improper periods, within the claim, for step designations such as "a." etc. It is suggested to amend these designations to either "(a)" or "(a)", for example.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

Art Unit: 1631

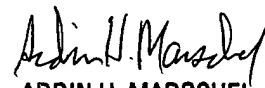
(November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)).
The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 9, 2004


ARDIN H. MARSCHEL
PRIMARY EXAMINER